IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

 Inventor:
 Lootz et al
 Examiner:
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 Ser. No.
 09/939.211
 Group Art Unit:
 3731

Title: REPOSITIONABLE STENT

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STATEMENT ACCOMPANYING REQUEST FOR PRE-APPEAL BRIEF REVIEW

A pre-appeal brief request for review is made herewith. The Applicants maintain that the Examiner has not established a prima facie case of obviousness of the pending claims. Claims 1, 5, 6, 8-10, 12-18, 20, 44, 64, 67, 70, 71, 74-77, 81, 82, 85, 86, 89, 90, 94, 100 and 105-122 stand rejected as being unpatentable over U.S. Patent 6,190,406 to Duerig et al. ("Duerig") in view of U.S. Pat. No 6,918,928 to Wolinsky et al. ("Wolinsky") under 35 U.S.C. § 103(a). The Applicants maintain that the Examiner has mischaracterised the content of the prior art and has used hindsight in rejecting the claims.

To establish a prima facie case of obviousness, three requirements must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. There must also be a reasonable expectation of success and the prior art reference or references must teach or suggest all of the claim limitations. (MPEP § 2143.) The Examiner maintains that Duerig discloses a plurality of annular support portions comprising bar elements and connecting bars, wherein the connecting bars engage a region of the first annular support portion that projects in the longitudinal direction and wherein the connecting bars engage a central portion of the second annular bar element portions. (Paper No./Mail date 20060203, page 2.) The Examiner acknowledges that Duerig does not teach a direction of curvature changing in the central region of the bar element when the stent is in the first position, but maintains that Wolinsky provides such a teaching to provide "the advantage of enabling the links 25 to fit together more closely in a nested arrangement with the

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undulation of rings 20a-c." (*Id.*, pp. 2-3.) The Applicants maintain that this is a mischaracterization of the content of Wolinsky.

As stated in a previous response (mailed 3 December 2005, page 2), Wolinsky teaches that it is the approximate equality of the portion of the rings that extends in the circumferential direction at the inflection point to the width of the link that provides the advantageous nested arrangement. (Wolinsky, column 6, lines 33-42.) In the final office action, the Examiner repeats the allegation that the inflection point of Wolinsky is the feature "that provides the advantageous nested arrangement." (Paper No./Mail date 20060203, page 5.) To support this contention, the Examiner cites a portion of Wolinsky (column 3, lines 43-47) that describes the inflection points. However, this passage provides no teaching or suggestion as to the inflection points aiding in creation of a nesting arrangement. Contrary to the Examiner's assertion, Wolinsky does not teach that the inflection points provide this advantage. The Examiner also continues to ignore the fact that Wolinsky also provides the advantage of "nesting" for the embodiment illustrated in Fig. 2, which shows no inflection points, as also stated previously (Wolinsky, column 5, line 53 – column 6, line 8). Additionally, there is no indication that Duerig does not provide a stent that adequately "nests" in the unexpanded state.

The Examiner concedes that it "may be true" that the embodiments shown in Figs. 2-4 of Duerig show adequate nesting, but further states that he relies on the embodiment described in column 5, lines 46-53, but not shown in any Figures of Duerig. (Paper No./Mail date 20060203, page 5). The Examiner additionally maintains that in this embodiment, "a nesting problem could exist..." (Id., page 6, emphasis added). This is sheer speculation on the part of the Examiner, as evidenced by the equivocal language used. It further demonstrates that the Examiner has impermissibly used the disclosure of the present application to find elements of the present invention in the prior art. The Examiner has taken what he considers could have been a problem with certain embodiments of the invention of Deurig and uses the teaching of Wolinsky to solve this "problem" despite the fact that other disclosed embodiments of Deurig clearly do not display this speculative "problem." Furthermore, Deurig is silent as to this problem being present in the embodiments relied upon by the Examiner. Therefore, the Examiner has misconstrued the scope and content of the prior art to conclude that one of skill

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in the art would have been motivated to combine the teachings of Duerig and Wolinsky to arrive at the present invention.

One of ordinary skill in the art also would not find any other suggestion or motivation to combine the teachings of Duerig and those of Wolinsky (see response mailed 3 December 2005, page 3). Therefore, one of ordinary skill in the art would have had no expectation of success in combining the teachings of these references to provide a stent allowing for a partially deployed stent to be withdrawn into a sheathing device without hooking engagement between the stent and the sheathing device.

Finally, the Examiner stated that Wolinsky alone, in Figure 6, discloses all of the features of claim 1. (Paper No./Mail date 20060203, page 6). However, Fig. 6 of Wolinsky clearly shows a stent having connecting bars that engage central portions of both first and second neighboring annular support portions, and not connecting bars that engage a region of the bar elements of a first annular support portion that projects in the longitudinal direction and a central portion of the second annular support portion, as recited in claim 1. Neither does Wolinsky disclose all the features of claim 5, which recites that the connecting bars engage the bar element portions of the first annular portion near a turning point of the first annular support portion. Nor does Wolinsky disclose all the features of claim 6, which recites that the connecting bars engage the bar element portions of the first annular portion at a point that projects furthest in the longitudinal direction.

Therefore, the Examiner has mischaracterized the content of the prior art and has not established a suggestion or motivation to combine the reference teachings, or a reasonable expectation of success in combining those references. Additionally, the prior art references do not teach or suggest all of the claim limitations. For these reasons, the Applicants maintain that a prima facie case of obviousness has not been established and that the current rejection of the claims is based on the impermissible use of hindsight to combine elements found or thought to be found in the prior art to arrive at the present invention. Withdrawal of the rejection of the claims under 35 USC § 103(a) and the issuance of a Notice of Allowance is respectfully requested.

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The final Office action was mailed on 8 February 2006. A petition for an extension of time of one month is hereby made with this appeal and request for pre-appeal brief review. The Commissioner is authorized to charge any fee required with the filing of this response or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

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